DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Arthromeda, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

December 16, 2014

Re: K142944
Trade/Device Name: ArthroPlan Digital Templating Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 2, 2014
Received: December 3, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A. Ochs

Robert A. Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142944

Device Name
ArthroPlan Digital Templating Software

Indications for Use *(Describe)*

ArthroPlan™ is indicated for use by suitably licensed and qualified healthcare professionals requiring access to medical images to be used in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the size and geometry of the prosthetic/fixation device when planning a potential hip arthroplasty surgical procedure. Templating is done without alteration of the original image, using scaling and measurement tools in a digital environment, in conjunction with manufacturers' templates available via the ArthroPlan library of digital templates for prosthetic and fixation devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Arthromeda's ArthroPlan™ Digital Templating Software

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Arthromeda®, Inc.
Phone: 513-236-0857
Facsimile: 513-898-2106

Contact Person: Elsa Abruzzo

Date Prepared: August 29, 2014

Name/Address of Sponsor:

Arthromeda, Inc.
172 Middle Street, Suite 207
Lowell, Massachusetts 01852 USA

Trade Name: (ArthroPlan)	ArthroPlan™ Digital Templating Software
Common or Usual Name:	System, Image Processing, Radiological
Classification Name:	Picture Archiving and Communications System (PACS)
Classification:	Class II
Product Code and Regulation:	LLZ, CFR 892.2050
Classification Panel:	Radiology

Predicate Devices:

Predicate devices for the ArthroPlan™ Digital Templating Software, include the:

- Meridian Technique, Ltd., Orthoview™ (K063327)
- Agfa Healthcare Corporation Orthopedic Software For IMPAX Workstations (K071972)

Intended Use / Indications for Use

ArthroPlan™ is indicated for use by suitably licensed and qualified healthcare professionals requiring access to medical images to be used in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the size and geometry of the prosthetic/fixation device when planning a potential hip arthroplasty surgical procedure. Templating is done without alteration of the original image, using scaling and measurement tools in a digital environment, in conjunction with

manufacturers' templates available via the ArthroPlan library of digital templates for prosthetic and fixation devices.

Device Description

ArthroPlan™ is software designed and developed for preoperative planning, a.k.a. digital templating, for orthopedic operations. It includes tools for performing common measurements and drawings in combination with orthopedic implant manufacturer's electronic templates (provided in the ArthroPlan Template Library, which is part of the software). The measurements and scaling tools enable the user performing preoperative planning for orthopedic procedures. The software allows the user to capture the radiographic image, import it to the software, accurately scale the degree of magnification of the image, and overlay and manipulated (size, angle, rotate, invert, etc.) the desired electronic template(s) on the image facilitating the election of the appropriate size of prosthetic/fixing.

Technological Characteristics

The ArthroPlan is software that can be downloaded from Arthromeda's website via the Internet, installed on a personal computer, laptop, or workstation and unlocked using an Arthromeda, Inc. provided key. The key is single use, permitting only one installation of the software on one personal computer, laptop, or workstation and preventing any unauthorized use of the software.

The device consists of a standalone Microsoft Windows compatible software installed on a personal computer, laptop, or workstation. Access to the software is controlled through existing security measures on the computer, laptop, or workstation. Radiographic images are captured from normal viewing programs (such as PACS) available to the user and copied into the software for processing off-line. ArthroPlan does not provide access to these viewing programs. Patient confidentiality and patient identification is determined by the user on the off-line saved file. Image integrity is maintained during processing. ArthroPlan Software imports images at a 1 to 1 ratio using the bitmap format. During the saving of images, there is a potential loss of data. Saving of images using the APL or BMP format are recommended. Any other format potentially causes loss of data.

The captured, imported, and saved image may be retrieved and processed with the following functionality:

- Scaling of the radiographic image based on known size image marker within software program (original image is not altered)
- Selection of desired prosthetic and fixing device manufacturer, model, and size template for overlay and manipulation on image
- Overlay and manipulation (size, angle, rotate, inverting, etc.) of the selected electronic template on the image

- Combine compatible prosthetic/fixing implant templates from different manufacturers

- Display, print, and archive reports (final images with template overlay including manufacturer name, model, size, measurements, etc.)

- Receive and store templates for prosthesis and fixation supplied by Arthromeda, Inc. for particular manufacturers' ranges of products

- Provide traceability of operator, date, and decision made

Performance Data

Performance testing including a non-clinical user validation was conducted on the ArthroPlan software. Testing was conducted in compliance to the applicable guidances and standards including:

Table 1: Applicable Standards and Guidances

FDA Guidance (January 11, 2002)	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
FDA Guidance (May 11, 2005)	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
ISO 62304	Medical Device Software – Software life cycle processes
ISO 62366	Medical Devices –Application of usability engineering to medical devices.
IEC/ISO 10918-1	Digital compression and coding of continuous-tone still images: Compliance testing
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM) Set
ANSI/AAMI HE75	Human Factors engineering – Design of medical devices

In all instances, the ArthroPlan functioned as intended and all results of the user and software validations observed was as expected.

Risk analysis indicates that ArthroPlan is identical to the predicate devices in the patient environment. ArthroPlan uses similar materials and constructional principles to the predicate device. ArthroPlan processes data in the form of images collected (captured) in the patient environment after the event of actual collection. This non-patient contact processing is described exactly in terms of its software functions and associated templates. For these reasons the non-clinical user validation conducted is sufficient to verify the functionality of the ArthroPlan.

Performance testing of the ArthroPlan Digital Templating Software indicates that it meets is specifications and performs as intended. In particular, the following functions have been tested and confirmed as operating according to specified requirements and being substantially equivalent to the predicates:

- Patient and procedure selection
- Image collection (capture) and scaling
- Procedure planning
- Templating
- Committing and saving operating session data
- Compilation and printing of associated reports

Substantial Equivalence

The ArthroPlan Digital Templating Software is as safe and effective as the Meridian Technique, Ltd., Orthoview™ (K063327) and Agfa Healthcare Corporation Orthopedic Software For IMPAX Workstations (K071972) predicate devices. The ArthroPlan has the intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the ArthroPlan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ArthroPlan software is as safe and effective as above cited predicates. Thus, the ArthroPlan is substantially equivalent.

Table 2: Comparison of Technological Characteristics

Comparison of Technological Characteristics		
Characteristic	ArthroPlan	Predicate Devices
Device Type	Standalone Software for Digital Templating	Same
Computer Environment	Personal Computer, laptop, workstation/server	Same
Clinical Use Case	Used for planning orthopedic procedures using templates in the areas of prosthetic placement.	Same
Principle of Operation	On captured radiographic image, the user identifies physiological landmarks and software calculates commonly used measurements based on those landmarks. The software also allows the user to overlay electronic templates of orthopedic implants provided by implantable device manufacturers.	Same
Means of radiographic image collection	Obtained from pre-obtained digital images via PACS system	Same
Processing of Data	Processes data to provide prosthetic and fixing template overlay and placement	Same
Templating Features	Scaling, measurement, template manipulation (sizing, moving, rotation, inverting, angling, etc.)	Same
Templates	Library of manufacturer electronic templates available in software	Same
Patient Contact	No patient contact	Same
Human Intervention for Interpretation of Images	Requires physician to use and interpret data. Decision on implant selection is up to the physician.	Same

Conclusions

The ArthroPlan Digital Templating Software is substantially equivalent to the predicate devices in intended use and technology. Performance incompliance to the applicable guidances and standards demonstrates that the ArthroPlan software devices is as safe, as effective, and performs equivalently to the predicate devices.